Audit, Review, and Compliance (ARC) Branch Policies for USDA Process Verified Program

1. Purpose

This document provides the policies for programs that are submitted to the ARC Branch for approval under the USDA Process Verified Program.

2. Scope

This document applies to all programs submitted for approval under the USDA Process Verified Program and includes all programs that are currently approved.

3. Policies

3.1. Breed Claims

Breed claims that are not supported by a recognized Breed Association are not eligible for verification under the Programs.

The ARC Branch will allow verification of the following breed activities:

- 1. Verification that breed association requirements for the specific breed are met; and
- 2. Verification that offspring originate from breed stock that meet breed association requirements for the specific breed.

Companies requesting verification of breed activities must (1) identify the applicable breed association and (2) submit the breed association's requirements for the specific breed.

3.2. Agricultural Products Data Services

Data services may or may not validate the data that is entered into an approved USDA Process Verified Program data system. However, the company must clearly distinguish between the validated and non-validated data. Data that is not validated may not be used to meet the requirements of other AMS marketing programs.

Data must be validated through on-site evaluations and data evaluations. Data validation must be addressed within the receiving process under the Programs. See Section 3.3 of this document for further information.

Companies do not need to re-validate data from another company which is already approved by the ARC Branch.

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3.3. Approved Supplier Evaluations Process

In accordance with the receiving process under the USDA Process Verified Program, a company must have a documented procedure that describes the criteria and process for supplier selection, evaluation, approval, and re-evaluation. A supplier is defined as an organization or person that provides a product, service, or information to a company. A supplier may be internal or external to the organization; and in a contractual situation, a supplier may be called "contractor".

Companies do not need to conduct onsite evaluations of suppliers who are already approved under a USDA Process Verified Program. Companies must conduct onsite evaluations and re-evaluations for suppliers which they approve. An "approved suppliers" listing must be maintained and made available for review during the USDA Process Verified Program audit.

Accordingly, companies must conduct an initial on-site evaluation of each supplier prior to approving the supplier under the program. Companies must conduct re-evaluations in accordance with one of the following policies:

- 1. 100% of the suppliers receive yearly onsite re-evaluations;
- 2. 10% of the suppliers or 2 suppliers, which ever is greater, randomly selected to receive a yearly onsite re-evaluation; or
- 3. 100% of the suppliers receive yearly onsite re-evaluations. When no non-conformances are identified, those suppliers receive an onsite re-evaluation once every 2 years.

All evaluations and re-evaluations must be in accordance with the *Principles of Auditing* as defined in *ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing*. These principles make the audit (evaluation or re-evaluation) an effective and reliable tool in support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to theses principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances.

The following principles relate to the auditor (the person conducting the evaluation or re-evaluation).

- a) Ethical conduct: the foundation of professionalism: Trust, integrity, confidentiality, and discretion are essential to auditing.
- b) Fair presentation: the obligation to report truthfully and accurately: Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and auditee are reported.
- c) Due professional care: the application of diligence and judgment in auditing: Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

Further principles relate to audits, which is by definition independent and systematic.

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- d) Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions: Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions will be based only on the audit evidence.
- e) Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process: Audit evidence is verifiable. It is based on samples of information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed on the audit conclusions.

3.4. Ranch or Farm Profiles

When a ranch or farm profile is required in a USDA Process Verified Program, the profile must be sufficient to allow verification of the desired claim. The profile must be available for review by the company, and when necessary by the USDA auditor. The profile is considered confidential information and should not be removed or copied during the audit process. The following are types of information that should be included in the profile in order to meet claim verification requirements:

- 1. A description or name of the of the supplier;
- 2. Maps and/or descriptions of specific locations where animals are maintained;
- 3. Number of acres;
- 4. Feeding practices;
- 5. Number of breeding stock;
- 6. Purchase of outside stock;
- 7. Breeding methods and seasons;
- 8. Birthing seasons;
- 9. Name of veterinarian:
- 10. Identification of animals:
 - a. Group identification Identification must be unique to the ranch and individual animals must be identified.
 - b. Individual identification Identification must be unique to the individual animal.
- 11. Documented procedures specific to the ranch or farm that address all program requirements; and
- 12. Records to support the ranch or farm profile.

3.5. USDA Process Verified Shield and Term

Companies must have a defined process for ensuring that the shield or term is used appropriately. This process can not be solely to rely on the ARC Branch for approval. Companies that use the USDA Process Verified shield or the term "USDA Process Verified" in promotional material must ensure that the shield or term is used in direct association with a clear description of the specified process verified points. Companies must also ensure that the shield or term are not misrepresented and are not used in association with any company claims.

The use of the USDA Process Verified shield on a label must meet one of the following conditions:

1. The specified process verified points are printed immediately adjacent to the USDA Process Verified shield.

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- 2. An asterisk referring the consumer to the information panel for further information about the specified process verified points is printed with the USDA Process Verified shield
- 3. An asterisk referring the consumer to point of sale information is printed with the USDA Process Verified shield. In this situation, the company must ensure that the point of sale information is readily available and within close proximity of the display counter containing the product.

The ARC Branch provides a cursory review of proposed labels but does not provide an official approval. Official approval of all labels must be received from the USDA Food Safety Inspection Service, Labeling and Consumer Protection Staff. The label application form and its instructions are available at http://www.fsis.usda.gov/fsisforms/7234-1.pdf.

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